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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,043	02/05/2004	Maher N. Qabar	5808.04	4992

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/774,043	QABAR ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-14 and 30-53* is/are pending in the application.

4a) Of the above claim(s) *30-32,34-45 and 48-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-14,33,46,47 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/4/04,2/7/06,2/9/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment and Response to the Restriction Requirement filed March 7, 2008 are acknowledged. Claims 1-9 and 15-29 are canceled. New claims 30-53 are presented. Accordingly, claims 10-14 and 30-53 are pending.

Applicants have elected without traverse Group II, drawn to methods of inhibiting a kinase, and, as the elected specie, the compound of new claim 33.

Thus the subject matter initially under consideration are those methods of inhibiting a kinase comprising administering the compound of instant claim 33. Those methods of use comprising administering compounds other than that of instant claim 33 are presently withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions.

A Preliminary Amendment filed February 5, 2004 and a Supplemental Preliminary Amendment filed February 18, 2004 are further acknowledged. Updated priority information is noted. Support for the instant claims, however, was not found in U.S. Application Nos. 08/692420, 08/797915, Provisional Application 60/047067 or PCT/US97/13622. Accordingly, the earliest effective date is deemed to be February 12, 1998.

Information Disclosure Statements filed November 4, 2004, February 7, 2006 and February 9, 2006 are further acknowledged and have been considered.

A complete list of co-pending and related applications is requested when Applicants respond to this Office Action.

The abstract of the disclosure is objected to because it is not directed to the subject matter presently under consideration. Correction is required. See MPEP § 608.01(b).

The disclosure is objected to for the following informality: In claim 46 "edema" is incorrectly spelled.

Appropriate correction is required.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-14, 33, 46 and 53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 30 of U.S. Patent No. 7,053,214. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 30 is drawn to the treatment of ulcerative colitis, an inflammatory disorder, comprising administering a compound of the structure of claim 1. The compound of instant claim 10 is encompassed in claim one.

Claims 10-14, 33 and 53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 70 of U.S. Patent No. 6,372,744 and over claim 21 of U.S. Patent 6,245,764. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 70 and 21, respectively, are drawn to

inhibiting a kinase, i.e., a urokinase, comprising administering a compound of the structure of claim 1. The compound of instant claim 10 is encompassed in claim one.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 46 and 47 are rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, and, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to practice the invention. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 46 recites "treatment of cancer, angiogenesis, restenosis, edema, inflammation, asthma and arthritis." There is insufficient written description for this claim limitation in the disclosure.

M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

There is no description of critical parameters or working examples disclosed in the present specification that would lead one skilled in the art to immediately

envisage the present invention from the disclosure.

A description of the claimed invention with all of its limitations through words, structures, figures and/or diagrams that fully set forth the claimed invention, is required.

Adequate description requires more than a mere statement that treatment of cancer, angiogenesis, restenosis, edema, inflammation, asthma and arthritis is part of the invention. *Genetech Inc. vs. Nova Nordisk* states, "[A] patent is not a hunting license. It is not a reward for a search but a compensation for its successful conclusion and 'patent protection' is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" (42 USPQ 2d 1001, Fed. Circuit, 1997).

It is not clear Applicants were in possession of the full scope of the claimed methods at the time the invention was made. There is no reasonable expectation of success based merely on a showing of antithrombotic activity or protease inhibition. The amount of experimentation to practice the claimed method would be unduly extensive. Accordingly, the rejection of record of claims 46 and 47 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

No claim is allowed.

Qaber et al., WO 99/41276, is cited to show further the state of the art.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614

May 23, 2008